



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

D1170B

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

February 6, 1997

97-PHI-15

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Paul E. Simmons  
729 West Siddonsberg Road  
Dillsburg, Pennsylvania 17019

GEN.

SPEC.

RELEASE

F#

DATE

2/13/97

Reviewed by: *[Signature]*

Dear Mr. Simmons:

On January 28, 1997, your livestock dealing/hauling business, located at 729 Siddonsberg, Pennsylvania was visited by Food and Drug Administration (FDA) investigators David J. Hainer and Gregory E. Beichner in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow you offered for sale and slaughter for human food. Additional investigation by the Food and Drug Administration at the slaughterhouse, the auctionhouse, and the other livestock dealer/hauler involved has revealed a violation of Section 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 4, 1996 you delivered a cow, black tagged "5586," for sale for slaughter to [redacted]. The cow was subsequently purchased and delivered for slaughter for human food on March 4, 1996 to [redacted]. The subject cow was slaughtered on March 5, 1996. United States Department of Agriculture (USDA) analysis of tissue samples collected from the animal identified the presence of 4.1 ppm (parts per million) gentamicin in the kidney tissue. Gentamicin is not approved for use in cattle and therefore no tolerance has been established for gentamicin in edible bovine tissue. The presence of gentamicin in edible tissue from your animal causes the food to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

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Our investigation revealed that you pick up animals (cows) from various dairy farmers or producers and either (1) deliver them for sale for slaughter at auction ~~for sale for slaughter at auction~~ or (2) deliver them directly to the slaughterhouse for slaughter for human food. The investigation also revealed that you keep no records which would identify the farmer or producer of the animals which you deliver for sale for slaughter. Since you cannot identify the producer from whom you obtained the subject cow, you have assumed full responsibility for the illegal gentamicin tissue violation noted above.

The violation listed above is not intended to be all inclusive. It is your responsibility to assure that your operations are in compliance with the law. As a dealer or purchaser or hauler of an animal, you are frequently the individual who introduces or offers for introduction into interstate commerce, an adulterated animal. As such, you share responsibility for violating the Federal, Food, Drug, and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

- 1) implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,
- 2) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal then it should not be offered for human food.

As a cattle dealer/hauler it is your responsibility to assure that the animals you offer for slaughter have not been treated with unapproved veterinary drugs, or if the drugs are approved, that the levels do not exceed established limits. Animals treated with medications must be withheld from slaughter for the appropriate time period.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you knowingly purchased a medicated

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cow and subsequently sold the animal to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,



Diana J. Kolaitis  
District Director  
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director  
PA State Bureau of Animal Industry  
Agriculture Building  
2301 North Cameron Street  
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa  
USDA Northeast Regional Office  
701 Market Street  
2B South  
Mellon Independence Center  
Philadelphia, PA 19102-1516